(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 272 901 B2

(12) **NEW EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the opposition decision:
17.07.1996 Bulletin 1996/29

(45) Mention of the grant of the patent:
11.11.1992 Bulletin 1992/46

(21) Application number: **87311238.7**

(22) Date of filing: **21.12.1987**

(51) Int. Cl.[6]: **A61L 15/00**, A61L 31/00

(54) Surgical fabric with printed X-ray markers

Chirurgischer Gewebestoff mit aufgedruckten Röntgenstrahlenmarkierungen

Tissu chirurgical dans lequel sont imprimés des marqueurs pour rayons X

(84) Designated Contracting States:
AT BE CH DE ES FR GB IT LI NL SE

(30) Priority: **22.12.1986 US 944135**

(43) Date of publication of application:
29.06.1988 Bulletin 1988/26

(73) Proprietor: **JOHNSON & JOHNSON MEDICAL, INC.**
Arlington, Texas 76014 (US)

(72) Inventors:
- **Dyer, John**
  Randolph NJ 07869 (US)
- **Papp, Stephen, Jr.**
  Edison NJ 08817 (US)
- **Denny, Thomas A.**
  East Brunswick NJ 08816 (US)

(74) Representative: **Jones, Alan John et al**
CARPMAELS & RANSFORD
43 Bloomsbury Square
London, WC1A 2RA (GB)

(56) References cited:
EP-A- 0 160 560
EP-A- 0 215 475
GB-A- 795 870
GB-A- 858 787
GB-A- 1 049 353
GB-A- 2 064 325
US-A- 4 185 626

EP 0 272 901 B2

Description

This invention relates to X-ray detectable fabrics and, more particularly, to surgical swabs and sponges which include a printed X-ray detectable marker as an integral component of the sponge fabric.

Various absorbent fabric materials are used in surgical procedures for packing, wiping, and cleansing in or around the operating site. Typical products include surgical sponges such as 4x4 inch folded surgical gauze of nonwoven fabric, and woven, nonwoven and knitted laparotomy pads. Although standard operating room procedures require all materials brought into the operating area to be accounted for upon completion of the procedure, an occasional sponge may inadvertently be left in the patient. It is accordingly common practice in the medical field to include a radiopaque marker on all surgical sponges so that the presence or absence of a sponge in a patient experiencing difficulty after an operation can be determined by X-ray examination rather than by reoperating on the patient.

A common X-ray detectable marker used in conjunction with surgical sponges is a polymeric filament or ribbon loaded with an X-ray opaque filler material such as barium sulfate. Suitable polymeric materials include polyisobutylene, polyvinyl chloride and copolymers of vinyl acetate and vinyl chloride. Such X-ray detectable elements have been incorporated into sponge material by a variety of techniques. In the case of gauze swabs, a filament has been interwoven into the fabric of the gauze or fused to the surface of the fabric and folded into the sponge construction. In the case of laparotomy pads, an X-ray detectable ribbon has been enclosed in a seam stitched along one end of the pad, or an X-ray detectable filament has been incorporated into the woven handle strap of the pad or into the body of the pad fabric. In the case of nonwoven fabric sponges, the filament has been either heat fused onto the surface of the fabric or incorporated into the fabric by introducing the radiopaque element during the fabric manufacturing process.

DE-A-2 600 185 discloses a process for applying an X-ray detectable filament to a surgical sponge in which process the X-ray detectable filament, in molten form, is laid on the surface of the sponge. The sponge with the filament on it is passed between a pair of rollers to adhere the filament to the strip.

GB-A- Patent 858787 discloses a sponge into which is injected a dense X-ray opaque body generally having a globoid shape. In most cases, however, the X-ray detectable element has been preformed as a ribbon, yarn or monofilament, and it has been essential to securely attach the element to the sponge fabric since if the element is separated from the fabric during use, not only is the fabric no longer visible by X-ray, but the separated element is easily lost in the surgical field. ES-A-0 302 627 discloses processes for producing X-ray detectable sponges. It is suggested that a sponge may be coated with an opaque material by printing, screen printing or th lik .

For manufacturing considerations, it is desirable that the X-ray detectable marker be secured to the sponge in a continuous and reliable manner with a minimum of labor. A final consideration is that the X-ray detectable marker be easily identified in an X-ray image.

It is accordingly an object of the present invention to provide an improved X-ray detectable marker on a surgical sponge. It is a further object of this invention to provide a surgical sponge having a distinctive and easily detected radiopaque marker. It is a yet further object to provide a method for applying a radiopaque marker to the surface of a fabric in a rapid, continuous and economical manner. These and other objects of the present invention will be apparent from the ensuing description and claims.

Summary of the Invention

The present invention provides a method of preparing a surgical sponge as set out in Claim 1.

A surgical sponge made in accordance with the present invention comprises a fabric and a radiopaque marker bonded to said fabric in a visually distinctive pattern. The radiopaque marker is applied to the surface of the fabric by printing a radiopaque plastisol or latex emulsion onto the surface of the fabric in such a way that the surface fibers of the substrate fabric are encapsulated. Upon heat-setting, curing or coalescing, the radiopaque material is securely bound to the fabric so that it becomes an integral part of the fabric and cannot be readily removed. Plastisols and latexes which are soft, rubbery materials even when heavily loaded with barium sulfate or other radiopaque salt are used in the present invention.

The pattern of the X-ray detectable marker is determined by the structure of the underlying fabric and the nature of the application means. The marker may be applied to the surface of the fabric in a continuous process at a high rate of speed by printing with a gravure roll. Suitable compositions for the marker comprise biocompatible polymers containing an effective amount of barium sulfate and having a viscosity suitable for printing.

Description of the Drawings

Fig. 1 is a view in perspective of a folded surgical sponge having an X-ray detectable marker applied in accordance with the present invention.

Fig. 2 is a print of an X-ray image of a double thickness of a nonwoven fabric having two narrow X-ray detectable bands printed thereon.

Fig. 3 is a photograph of a nonwoven fabric having a radiopaque marker applied to the surface thereof.

Fig. 4 is a print of an X-ray image of the fabric of Fig. 3 illustrating the pattern of the X-ray marker.

Fig. 5 is a photograph of another nonwoven fabric having a radiopaque marker applied to the surface thereof.

Fig. 6 is a print of an X-ray image of the fabric of Fig. 5 illustrating the pattern of the X-ray marker.

Fig. 7 is a photograph of a surgical gauze having a radiopaque marker applied to the surface thereof and also containing a conventional X-ray detectable monofilament.

Fig. 8 is a print of an X-ray image of the fabric of Fig. 7.

Description of the Invention

The present invention consists of applying a plastisol or latex emulsion containing from 15 percent up to 70 percent by weight of barium sulfate onto the surface of surgical sponge fabrics. The plastisol or latex emulsion is applied by printing onto the surface of the fabric in a continuous or intermittent pattern. Upon heat-setting, curing or coalescing, the upper layer of fibers of the underlying fabric are encapsulated by the radiopaque material so that the marker is securely bound to the surface of the fabric and will not separate during normal handling or use.

The radiopaque marker is applied to the surface of the fabric in a distinctive pattern which is readily identified in an X-ray image. In the case of those fabrics having an open structure such as woven gauze and certain nonwoven fabrics, the radiopaque material may be applied to the fabric in such a way as to preserve the open spaces in the fabric whereupon the fabric structure itself becomes the distinctive pattern of the X-ray marker.

In the case of fabrics having no distinguishable pattern such as closely knit or tightly-woven fabrics or non-apertured nonwoven fabrics, it is preferable to apply the radiopaque material to the surface of the fabric in a predetermined pattern which is controlled by the configuration of the printing roll. Latex emulsions and plastisol formulations are applied to the fabric by padding, gravure printing, screen printing, or other convenient method.

Patterned nonwoven fabrics useful in the practice of the present invention may be prepared according to conventional hydraulic entanglement methods. In brief, these methods consist of providing a fibrous web of randomly oriented staple length fibers, positioning the web on a patterned, apertured belt, and subjecting the web to a plurality of high pressure hydraulic jets to entangle the fibers into a pattern conforming to that of the supporting belt. The entangled fibers are thereupon separated from the belt and dried on hot drums to produce a patterned nonwoven fabric. This method of manufacturing is described in detail in U.S.-A-3,068,547; 3,129,466; 3,485,706; 3,494,821; and 3,681,184 and is well known to those skilled in th art.

The nonwoven fabric may comprise any suitable combination of natural and/or synthetic textile materials including cotton, rayon, acrylics, polyester and nylon. A particularly preferred fiber composition is a blend of 70% rayon (1.5 denier, approximately 3 cm staple length) and 30% polyester (1.5 denier, approximately 3 cm staple length). The staple fibers are blended and converted to a fibrous web on conventional textile processing equipment such as a Rando-Webber which produces a web having random fiber orientation.

The nonwoven fabric preferably has a dry weight of from about 1.0 to 3.0 ozs per square yard (30 to 100 g/m^2), with the lighter weights limited by the processability of the fibrous web and the heavier weights limited by the desired utility and construction of the sponge or swab, although higher weights may be preferred for some product applications such as laparotomy pads.

The radiopaque composition is preferably dyed or pigmented blue or other suitable color which contrasts sharply with blood. The color permits ready identification of the X-ray detectable element in the sponge, facilitates sponge counting in the operating room and further helps locate the sponge when saturated with blood during use. As a characteristic of the sponges of the present inventin, the radiopaque material may be applied primarily to one surface of the fabric, and is consequently visually more apparent from that side. This increased visibility may be capitalized on when folding the sponge by placing the radiopaque material to the outside of the sponge.

Turning now to Figure 1 there is illustrated a surgical sponge, indicated generally by the numeral 10, which consists of folded fabric 11 having a radiopaque marker consisting of a pair of lines 12 and 13. The radiopaque marker lines are continuous over the length of the folded sponge and applied to the fabric during manufacture by printing a radiopaque plastisol directly onto the surface of the fabric. While lines 12 and 13 appear generally as two continuous lines of uniform width and depth, closer inspection reveals that the lines conform to the open pattern of the fabric and have a variable thickness on the surface of the fabric. The pattern of the radiopaque material on the fabric of the sponge results in the formation of a distinctive X-ray image of the radiopaque marker. Figure 2 is a print of the X-ray image of a double thickness of a fabric having two narrow X-ray detectable bands printed thereon. While the X-ray pattern is created entirely by the pattern of the underlying fabric, the fabric pattern itself is not apparent from the X-ray image due to the narrow width of the radiopaque lines.

Figure 3 is a photograph of an open patterned nonwoven fabric which is characterized by a series of small, widely-spaced fiber masses interconnected by radial threads in what is commonly referred to as a "rosebud" pattern. A radiopaque material applied uniformly to the fabric over a width of from about 1 to 2 cm, appearing as dark bands in Figure 3, encompasses a sufficient area of fabric to make the actual pattern of the fabric visible in the X-ray image as illustrated in Figur 4. Where such a side band of radiopaque material is applied to the fabric, it will usually be sufficient to apply the material in a

discontinuous line so that one or two bands of material appear in each sponge. For example, if the length of the fabric comprising each folded sponge is 0.5 m, it would be sufficient to apply the radiopaque material in bands of 2 cm wide by 10 cm long at a frequency of four bands per meter of fabric, thus assuring that each sponge would include two radiopaque markers, at least one of which would be a continuous 10 cm length.

Figures 5 is a photograph of another nonwoven fabric having a radiopaque marker applied to the surface thereof. The X-ray image of the fabric as illustrated in Figure 6 clearly shows the pattern of the fabric to be different than that of Figure 4.

Figure 7 illustrates a conventional 20x8 woven surgical gauze printed with a band of radiopaque plastisol material which appears as the dark bands in the photograph of Figure 7. The radiopaque material uniformly coats each yarn of the gauze within the area of the coating and the pattern of the gauze is readily identified in an X-ray image of the fabric as illustrated in Figure 8. Figures 7 and 8 also include a conventional monofilament marker which is clearly visible as the wavy line in the X-ray image of Fig. 8, and less evident in the photograph of the fabric of Fig. 7. It should also be noted that while the photograph and the X-ray are of the same fabric, the displayed areas are not precisely the same.

As illustrated in Figures 1-8, the radiopaque material may be applied to an open mesh fabric over an area sufficient to reveal the actual pattern of the underlying fabric in an X-ray image, or over an areas which is too narrow to disclose the repeating pattern of the fabric, but nevertheless displays a distinctive pattern of its own in an X-ray image as a result of the underlying fabric pattern.

In the case of closely knit or woven fabric, the radiopaque material is applied in a predetermined pattern controlled by the application means. For example, a plastisol may be applied to the surface of the fabric by screen printing or by gravure system in a continuous line or in discontinuous bands and in any desirable pattern. An infinite variety of patterns is, of course, possible and may be utilized in the practice of the present invention. One desirable pattern would be in the name or initials of the supplier of the surgical product and perhaps the order number of the product, which would not only provide X-ray detectability but also indicate the source of the product to the surgeon during the operating procedure. Since the surgical sponges are usually wadded up during use, it is unlikely that this information would be fully legible in an actual X-ray image, but even a single letter of the alphabet would be distinctive and easily recognized as a foreign object in an X-ray following a surgical procedure.

The method of the present invention is further illustrated in the following examples where all parts and percentages are by weight unless otherwise indicated.

Example 1

A plastisol printing composition is prepared from polyvinyl chloride resin according to the following formulation:

100 parts	Geon 125-A® PVC resin
100 parts	Dioctyl phthalate plasticizer
328 parts	$BaSO_4$
5 parts	blue pigment

Geon® 125-A PVC resin is a low molecular weight, low viscosity polyvinylchloride powder available from B.F. Goodrich, Avon Lake, Ohio. The $BaSO_4$ is suitably No. 1 Barytes® HP available from Pfizer, Inc., Easton, Pennsylvania. The blue pigment is suitably Ultramarine Blue available from Sun Chemical Co., Cincinnati, Ohio. The PVC resin is sifted with stirring into the dioctyl phthalate plasticizer containing the blue dye, followed by addition of the $BaSO_4$. The resulting composition contains 61.5% $BaSO_4$ and has a viscosity of about 20,000 cps which is suitable for printing. Desirable viscosities for printing are generally in the range of 5,000 to 20,000 cps although higher or lower viscosities may be utilized in some applications.

Example 2

An emulsion latex printing composition is prepared according to the following formulation:

25 parts	water
10 parts	blue pigment
2 parts	antifoam
4 parts	rheology modifier
3 parts	ammonia (28%)
200 parts	Rhoplex® K-3 (48%)
501 parts	$BaSO_4$

The latex printing composition is prepared by first combining the water, ammonia, antifoam, rheology modifier, pigment and Rhoplex® K-3, then slowly adding the $BaSO_4$ with stirring to obtain a mix with 67% $BaSO_4$ solids. The ammonia functions to increase the pH to about 8, the antifoam may be Colloids® 999 available from Colloids, Inc., Newark, NJ, and the rheology modifier may b a poly (ethylene oxide) such as Poly-ox® available from Union Carbide, Danbury, CN. Rhoplex® K-3, is a 46% aqueous acrylic emulsion available from

Rohm & Haas, Philadelphia, PA. After application to the fabric and removal of volatiles, the $BaSO_4$ content in the resulting polymeric composition is approximately 80 percent.

The radiopaque polymeric composition with $BaSO_4$ is naturally white, but may be pigmented blue or other color for enhanced visibility, or left uncolored except for some indication of its presence such as a thin blue line printed onto the marker after curing. A wide, unpigmented band of radiopaque material with a narrow blue line or the logo of the manufacturer printed thereon, may be more aesthetically pleasing to the surgeon and still provide all the advantages of a wide, X-ray detectable marker as described herein.

The plastisol or latex printing composition is applied to the surface of the surgical fabric using conventional printing equipment and techniques as, for example, by gravure rolls. The printed fabric is passed through a heating station to polymerize the resin and remove volatile components. The resulting polymeric deposit is securely adhered to the underlying fabric and typically comprises from 60-90% $BaSO_4$ solids in the resin binder. We have found that at least 10% resin binder is desirable to assure the integrity of the polymeric mass and its adhesion to the fabric.

The $BaSO_4$ used in the printing formulations of the present invention has an average particle size of at least 5 microns, and most preferably 10 microns or greater, in order to obtain printing compositions having the desired flow characteristics when containing up to 70% $BaSO_4$ solids. We have found that when the average particle size is substantially less than 5 microns, as for example 2 microns, formulations containing such high levels of $BaSO_4$ solids are essentially dry mixes not suitable for application to fabric by conventional printing means. In the case of the No. 1 Barytes HP used in the preceding examples, the average particle size is 10 microns with 75 percent of the particles being 5 microns or greater.

We have also found that the X-ray detectability of a cured latex or plastisol containing from 60 to 70 percent barium sulfate compares favorably with that of a conventional monofilament marker which usually contains about 60 percent barium sulfate. Moreover, the X-ray visibility of the radiopaque material is greater in the case of the present invention, since if the X-ray is taken in plan view, the pattern of the marker stands out while if the X-ray is taken in side view, the effective thickness of the marker is increased and the brightness of the marker in the X-ray image is enhanced.

The fabric may be printed on one or both sides with the radiopaque material and superimposed printing on both sides has the advantage of presenting thinner layers with greater surface area to speed drying or curing of the radiopaque material. Wide lengths of fabric may be printed with parallel bands of radiopaque material spaced to conform to the desired final width of the sponge so that the fabric may be slit within the bands. The radiopaque material thereby performs the dual function of stabilizing the cut edges of the fabric against loose yarns or linting, while at the same time imparting X-ray detectability to the fabric.

Claims

1. A method of preparing a surgical sponge comprising: printing on the surface of an absorbent fabric in a visually distinctive pattern a plastisol or latex emulsion containing from 15 to 70% by weight of barium sulphate having an average particle size of greater than 5 micrometers; and securely bonding said plastisol or latex emulsion to said fabric to provide an X-ray detectable marker thereon.

2. The method of claim 1, wherein said printing is gravure or screen printing.

3. The method of claim 1 or claim 2, wherein said plastisol is a PVC plastisol.

4. The method of claim 1 or claim 2, wherein said latex emulsion is an acrylic latex emulsion.

5. The method of any one of claims 1 to 4, wherein the plastisol or latex emulsion contains from 60 to 70% of the barium sulphate.

Patentansprüche

1. Verfahren zur Herstellung eines chirurgischen Schwammes, umfassend: das Aufdrucken eines Plastisols oder einer Latex-Emulsion, die von 15 bis 70 Gew.-% Bariumsulfat enthält, das eine mittlere Teilchengröße von mehr als 5 µm hat, auf die Oberfläche eines absorbierenden Stoffes; und das sichere Verbinden des Plastisols oder der Latex-Emulsion mit dem genannten Stoff zur Erzielung einer durch Röntgenstrahlen nachweisbaren Markierung auf demselben.

2. Verfahren nach Anspruch 1, bei dem das Druckmittel Tiefdruck oder Siebdruck ist.

3. Verfahren nach Anspruch 1 oder Anspruch 2, wobei das Plastisol ein PVC-Plastisol ist.

4. Verfahren nach Anspruch 1 oder Anspruch 2, wobei die Latex-Emulsion eine Acryl-Latex-Emulsion ist.

5. Verfahren nach einem der Ansprüche 1 bis 4, wobei das Plastisol oder die Latex-Emulsion 60 bis 70% des Bariumsulfates enthält.

Revendications

1. Procédé de préparation d'une compresse chirurgicale consistant à : imprimer sur la surface d'un tissu absorbant, selon un motif distinctif visible à l'oeil nu, un plastisol ou une émulsion de latex contenant de

15 à 70 % en poids de sulfate de baryum ayant une dimension moyenne de particules de plus de 5 micromètres ; et fixer solidement ledit plastisol ou ladite émulsion de latex audit tissu pour former sur ce dernier un marqueur détectable aux rayons X.

2. Procédé selon la revendication 1, dans lequel ladite impression est une impression par gravure ou à l'écran de soie.

3. Procédé selon la revendication 1 ou la revendication 2, dans lequel ledit plastisol est un plastisol de PVC.

4. Procédé selon la revendication 1 ou la revendication 2, dans lequel ladite émulsion de latex est une émulsion de latex acrylique.

5. Procédé selon une quelconque des revendications 1 à 4, dans lequel le plastisol ou l'émulsion de latex contient de 60 à 70 % de sulfate de baryum.

FIG-1

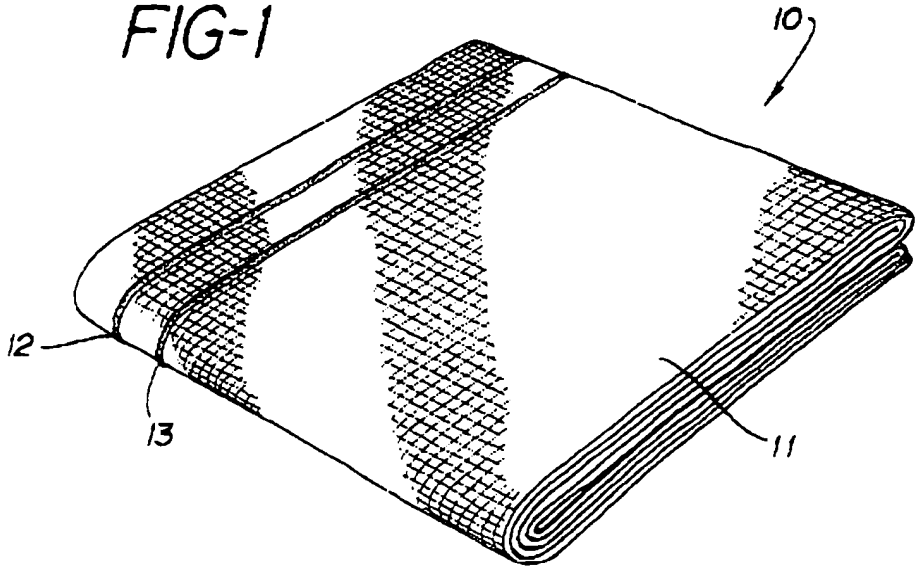

FIG-2

FIG-3

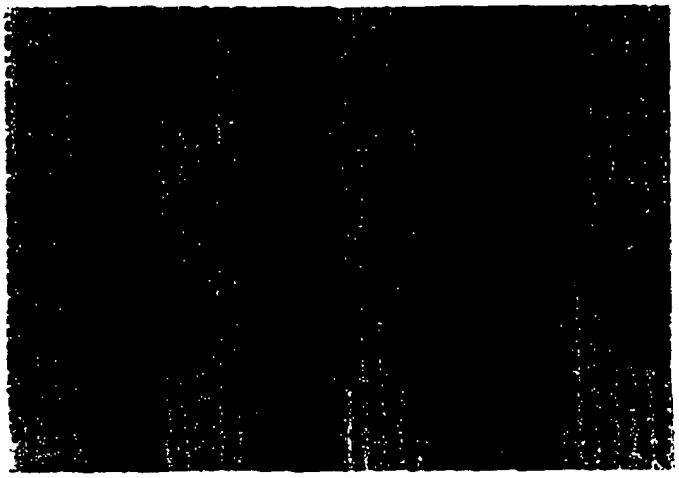

FIG-4

FIG-5

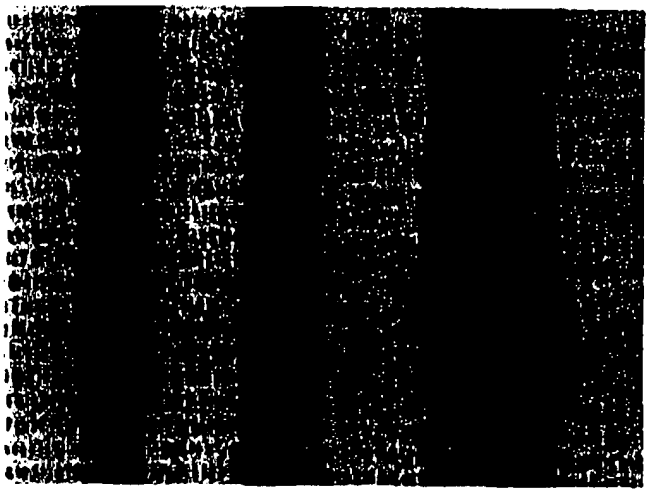

FIG-6

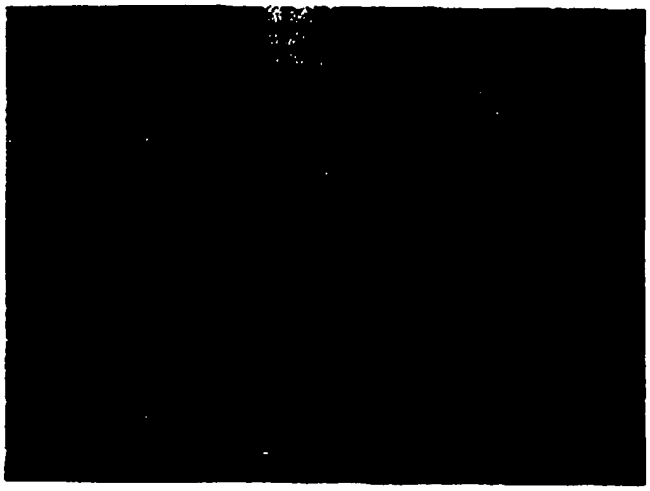

FIG-7

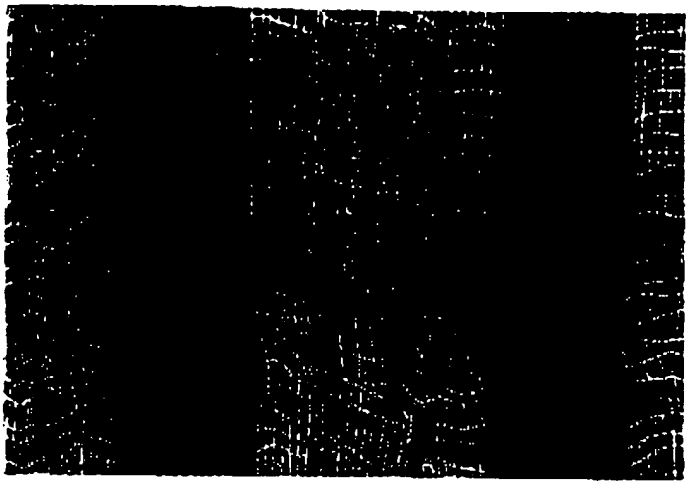

FIG-8